K042953

NOV 2 2 2004

III. 510(K) Summary

SUBMITTED BY:

Globus Medical Inc.
303 Schell Lane
Phoenixville, PA 19460
(610) 415-9000 x218
Contact: Kelly J. Baker

DEVICE NAME:

PROTEX™ Stabilization System

CLASSIFICATION:

Per 21 CFR as follows:
§888.3050 Spinal Interlaminal Fixation Orthosis
§888.3060 Spinal Intervertebal Body Fixation Orthosis
§888.3070 Pedicle Screw Spinal System
§888.3070 Spondylolisthesis Spinal Fixation Device System
Product Codes MNH, MNI, KWQ, KWP, NKB.
Regulatory Class III
Panel code 87.

PREDICATE DEVICES:

PROTEX™ Stabilization System K040442, SE date May 20, 2004
ISOBAR Semi-rigid Spinal System K991326, SE date November 8, 1999

DEVICE DESCRIPTION:

The PROTEX™ Stabilization System consists of a variety of shapes and sizes of rods, hooks, monoaxial screws, polyaxial screws, locking caps, t-connectors, staples, and associated manual surgical instruments. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. AccuRods are intended for posterior use with polyaxial and monoaxial screws only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod.

The implants are composed of titanium alloy as specified in ASTM F136 and F1295.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2004

Kelly J. Baker, Ph.D.
Project Manager, Quality Assurance and Regulatory Affairs
Globus Medical, Inc.
303 Schell Lane
Phoenixville, Pennsylvania 19460

Re: K042953
Trade/Device Name: Globus Medical PROTEX™ Stabilization System
Regulation Number: 21 CFR 888.3050, 888.3060, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: October 25, 2004
Received: October 26, 2004

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications for Use Statement

510(k) Number: K042953

Device Name: PROTEX™ Stabilization System

Indications:

The PROTEX™ Stabilization System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the PROTEX™ Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as a posterior non-pedicle screw fixation system, the PROTEX™ Stabilization System is intended for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's disease), fracture, pseudarthrosis, tumor resection, and/or failed previous fusion. Overall levels of fixation are T1-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the PROTEX™ Stabilization System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

for (Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K042953